Office of Research Integrity (ORI)

Review of Policies and Procedures for Addressing Research Misconduct Allegations

As Required by 42 CFR Part 93

Institution: University of New Mexico Health Sciences Center (UNM)

Date: December 2, 2014

A review of the UNM Faculty Handbook – E40: Research Misconduct policy for responding to research misconduct allegations indicates that the following requirements of the research misconduct regulation at 42 CFR Part 93[1] either are or are not appropriately reflected in the institution's policies and procedures, as noted in the comment sections below.[2] The comment section(s) indicate the needed modification(s).

Applicability

Establishes policies and procedures according to 42 CFR Part 93, keeps them in compliance with this part, and upon request, provides them to ORI, other U.S. Department of Health and Human Services (HHS) personnel, and members of the public (§93.302(a)).

Comment: Partially Addressed – The policy notes certain requirements for reporting to ORI when U.S. Public Health Service (PHS) funding is involved but does not reference the citation (42 CFR Part 93).

Relationship to PHS Support. Applies to allegations of research misconduct involving: "institutional members," as defined in § 93.214,[3] and one or more of the following: (1) applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information; (2) PHS supported research, research training, or activities related to that research or research training; or (3) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training (§93.102).

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[1]This form does not encompass all of the obligations of institutions under 42 CFR Part 93.

[2]Under § 93.319 institutions may have internal standards of conduct different than those set forth in 42 CFR Part 93. An institution may find conduct to be actionable under its standards, even if the action does not meet the definition of research misconduct in the HHS regulation.

[3]Institutional member or members means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

Comment: Partially addressed – The introduction section of the policy notes that the policy applies to most, if not all, members of the University's academic community, but there are only general references to PHS funding.

Time Limitations. Includes or incorporates by reference the limitation to research misconduct occurring within six years of the date that HHS or the institution receives an allegation of research misconduct.[4]

Comment: Not addressed.

General Policies and Principles

Informs its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures (§93.302(a)(2((I)).

Comment: Partially addressed – The policy is found in the faculty handbook, but there is no further information on how the requirements are further disbursed to faculty and staff.

Defines allegation as any disclosure of possible research misconduct through any means of communications, i.e., by written or oral statements or other communications to an institutional or HHS official (§93.201).

Comment: Not properly addressed – The policy, in Section 3.3, states that "allegations must be made in writing, and signed and dated by the complainant." The PHS regulation requires institutions initiate an inquiry into allegations of research misconduct if the allegations are "sufficiently credible and specific" without qualification. Anonymous and/or oral allegations that are credible and specific must be addressed.

Defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results (§93.103).

Comments: OK, Section 2.9.

An ORI finding of research misconduct requires that there be a significant departure from accepted practices of the relevant research community, that the misconduct be committed intentionally, knowingly, or recklessly, and the allegation be proven by the preponderance of the evidence (§93.104, 106(a)).

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[4]Time limit exceptions: (1) continuation of renewal of any incident of research misconduct that occurred before the 6-year limit through the citation, republication, or other use for the potential benefit of the respondent of the research record that is the subject of the allegation, (2) alleged research misconduct that, if it occurred, would have a substantial adverse effect on the health or safety of the public, as determined by ORI or by the institution in consultation with ORI, or (3) receipt of the allegation by HHS or the institution before June 16, 2005 (§93.105).

Comment: OK, Section 6.5.

Affording the affected individual(s) confidential treatment to the maximum extent possible (§93.108, §93.300(e)).

Comment: OK, Section 3.6.

Responding to each allegation of research misconduct in a thorough, competent, objective, and fair manner (§93.300(b)).

Comment: Policy generally meets this criteria.

Notify ORI immediate if the health and safety of the public is at risk, if HHS resources or interests are threatened, if research activities should be suspended, if federal action is required to protect the research misconduct proceedings, if the alleged incident might be publically reported, or if the research community or public should be informed (§93.318). If a reasonable indication of possible criminal violations is found, ORI must be notified immediately (§93.318(d)).

Comment: Generally OK, Section 8.1.5.

Provides for appropriate interim institutional actions, such as additional monitoring of the research process or the handling of federal funds or equipment, reassignment of personnel, or additional review of research data and results, during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process (§93.304(h)).

Comment: OK, Section 8.3.

Preparation and maintenance of the documentation of the research misconduct proceedings in a secure manner for at least seven (7) years after completion of any PHS proceedings involving the research misconduct allegations (§93.317(b)) and providing them to ORI or other HHS personnel upon request (§93.309(d)).

Comment: Retention terms for inquiry (3 years) and investigations (5 years) do not meet the current requirement of 7 years after the completion of the proceedings.

Provides for reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses and committee members and protect them from actual or potential retaliation by respondents or other institutional members (§§93.300(d), 93.304(l)).

Comment: OK, Section 7.3.

Make all reasonable and practical efforts to protect or restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed (§93.304(k)).

Comment: OK, Section 7.2.

Notify ORI in advance if the investigation process is to close prematurely, based on the admission of guilt or settlement agreement with the respondent, or for any other reason (§93.316).

Comment: OK, Section 8.1.2.

Enforcing any HHS administrative actions imposed on institutional members (§93.300(h)).

Comment: Not addressed.

Assessment of Allegations to Determine if an Inquiry is Warranted

Provides for assessment of the allegation to determine if an inquiry is warranted because the allegation: (1) is within the definition of research misconduct in § 93.103; (2) is an allegation to which the research misconduct regulation applies under § 93.102; and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified (§ 93.307(a)).

Comment: Generally OK, Section 4.3.

Inquiries

The purpose of an inquiry is to perform an initial review of the evidence to determine whether to carry out an investigation; a full review of all of the evidence related to the allegation is not needed (§ 93.307(c)).

Comment: OK, Section 5.1.

On or before the respondent is notified of the research misconduct allegations, take all practical steps to sequester, inventory, and secure the research record and other relevant evidence (§93.305(a), §93.307(b), §93.310(d)(2)), and after sequestration, allowing the respondent copies of, or reasonable, supervised access to the research records (§93.305(b)).

Comment: Generally OK, Section on "Securing Research Record" (section number missing, but passage should be identified as Section 6.2.)

Completion of each inquiry within 60 calendar days from receipt of allegation (§93.307(g)), including the receipt and evaluation of comments by the respondent (§93.307(f)), and the preparation of a written report[5] (§93.307(e)). If the inquiry is not completed within the 60-day

[5]Inquiry report should include the name and position of the respondent, a description of the allegations of research misconduct, the PHS support involved, the basis for recommending an investigation, and any comments on the report by the respondent or complainant.

period, the reasons for exceeding that period will be included in the record of the inquiry (§93.307(g)).

Comment: OK.

Provide written notification to the respondent before an inquiry is initiated (§93.307(b)).

Comment: OK, Section "Securing Research Records."

Precautions against real or apparent conflicts of interest in inquiries (§93.300(b), §93.304(b)).

Comment: OK, Section "Inquiry Committee."

Provide the respondent an opportunity to review and comment on the inquiry report (§93.307(f)).

Comment: OK, Section "Inquiry Report."

Provide for documentation in inquiries in sufficient detail to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation (§93.309(c)).

Comment: Generally OK, under Section 8.5.

Initiate an investigation if the preliminary information-gathering and preliminary fact-finding from the inquiry indicate that the allegations may have substance (§93.307(d)).

Comments: OK, under Inquiry determination.

Investigations

Initiation of an investigation within 30 calendar days after a determination that an investigation is warranted (§93.310(a)).

Comment: OK, Section 6.1.

Notification to the Office of Research Integrity (ORI), PHS, prior to the initiation of an investigation (§93.310(b)), including a copy of the inquiry report (§93.309(a)).

Comment: OK, Section 8.1.1.

Selection of impartial experts to conduct investigations (§93.310(f)).

Comment: OK, Section 6.3.

Precautions against real or apparent conflicts of interest in investigations (§93.310(f)).

Comment: OK, Section 6.3.

Provide written notification to the respondent when a determination is made that an investigation is warranted (§93.308(a), §93.310(c)).[6]

Comment: OK, under "Inquiry Determination."

Provide for interviewing each respondent, complainant, and any other available person having information regarding any relevant aspect of the investigation, and recording and transcribing each interview, and providing the recording or transcript to the interviewee for correction (§93.310(g)).

Comment: OK, Section 6.4.

Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion (§93.310(h)).

Comment: Not specifically stated, but generally implied.

Completion of an investigation within 120 calendar days (§93.311(a)), including the preparation of the report of findings, providing the draft report for comment (§93.312), and sending to ORI the investigation report.

Comments: OK, Section 6.6 and 6.5.

If unable to complete the investigation in 120 days, the institution must ask ORI for an extension in writing (§93.311(b)).

Comment: OK, Section 8.1.3.

Provide the respondent an opportunity to review and comment on the draft investigation report and, concurrently, a copy of (or supervised access to) the evidence on which the report was based (§93.312(a)).

Comment: Partially met– Section 6.5 provides the respondent an opportunity to review and comment on the draft report, but there is no specific provision to provide access to the relevant evidence on which the report was based.

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[6]The institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation.

At the completion of the investigation process, provide ORI with the investigation report[7] (including the report, all attachments, and any appeal), the final institutional actions (that is, was there research misconduct, and if so, who was responsible), the institutional findings (the institution's acceptance of the investigation's findings) and any administrative actions against the respondent (§93.315).

Comment: The provision is generally met by procedures in Section 6.6, Institutional Review and Determination.

Institution Appeal Process

If an institution's procedures provide for an appeal by the respondent that could result in the reversal or modification of the findings of research misconduct in the investigation report, the institution must complete any such appeal within 120 days of its filing. Appeals from personnel or similar actions that would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit.

Comment: Not applicable – The appeal process in this policy is limited to claims of procedural error, or a claim that the sanctions imposed as a result of a finding of research misconduct were inappropriate.

[7]Body of report to include the allegations, the PHS support, the institutional charge, the policies and procedures, the research records and evidence, the statement of findings (§93.313(f)), and comments by the respondent and complainant (§93.313).